

including fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation, has been approved under OMB control number 0910-0765.

In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: October 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0001]

Office of Minority Health and Health Equity Public Meeting on Strategies To Improve Health Equity Amidst the Opioid Crisis; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled “Office of Minority Health and Health Equity Public Meeting on Strategies to Improve Health Equity Amidst the Opioid Crisis.” The purpose of this public meeting is to share information and obtain the public’s perspectives on the current opioid crisis and how it specifically affects racial and ethnic minority, underrepresented, and underserved populations across the country, approaches to prevent and treat opioid use disorder, and emerging research to improve care, and explore how FDA can support those efforts.

DATES: The public meeting will be held on November 21, 2019, from 9 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Hilton Washington, DC/ Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852, 301-468-1100.

FOR FURTHER INFORMATION CONTACT: Jovonni Spinner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2384, Silver Spring, MD 20993, 301-796-8729, Jovonni.Spinner@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Minority Health and Health Equity’s (OMHHE) mission is to “promote and protect the health of diverse populations through research and communication that addresses health disparities.” Racial and ethnic minorities have experienced an increase in opioid-involved overdose deaths over the past few years. For example, the rate of opioid-involved overdose death nearly doubled among Black/non-Hispanic populations between 2015 (6.6 per 100,000 population) and 2017 (12.9 per 100,000 population) (Ref. 1). It has also been shown that racial and ethnic minority populations suffer from chronic pain at higher rates than other populations and the evaluation and treatment for pain management may vary across ethnic groups (Ref. 2). The opioid crisis is a multifaceted issue and our aim is to convene diverse stakeholders to stimulate dialogue that will highlight and bring about solutions to improve the health of the communities we serve. Meeting discussions will inform future programming for the OMHHE.

II. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: <https://www.eventbrite.com/e/fda-omhhe-strategies-to-improve-health-equity-amidst-the-opioid-epidemic-tickets-70822278341>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Anonymous registration is available. Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by 11:59 p.m. Eastern Time, November 15, 2019. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided

beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting/public workshop.

If you need special accommodations due to a disability, please contact Jovonni Spinner at 301-796-8729 or Jovonni.Spinner@fda.hhs.gov no later than November 7, 2019.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast: <https://www.eventbrite.com/e/fda-omhhe-strategies-to-improve-health-equity-amidst-the-opioid-epidemic-tickets-70822278341>.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Henry, J., Kaiser Foundation, “Opioid Overdose Deaths by Race/Ethnicity.” Available at: <https://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/?dataView=2&activeTab=graph¤tTimeframe=0&startTimeframe=18&selectedDistributions=white-non-hispanic--black-non-hispanic-hispanic&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%7B%22Location%22,%22sort%22:%7B%22asc%22%7D>. Accessed on September 9, 2019.
2. Campbell, C.M. and R.R. Edwards, “Ethnic Differences in Pain and Pain Management.” *Pain Management*, vol. 2(3), pp. 219-230, 2012.*

Dated: October 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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